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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
CARLSON, KAREN C	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,552	FISHMAN, JAY A.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1(e, f), 6, 7, 8(g-l), 15-17, 18(e, f), 23, 24, and 26 (e, f)* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/03;11/04; 9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1 (a-d), 2-5, 8(a-f), 9-14, 18(a-d), 19-22, 25, and 26 (a-d) .

Applicant's election with traverse of SEQ ID NO: 3, Claims 1(e, f), 6, 7, 8(g-i), 15-17, 18(e, f), 23, 24, and 26 (e, f) in the reply filed on November 23, 2005 is acknowledged. The traversal is on the ground(s) that Applicants assert that the sequences depicted as SEQ ID NO: 1, NO: 2, and NO: 3 are structurally related as porcine retroviruses. This is not found persuasive because Applicants have not shown any structural relatedness of the polypeptides claimed, nor have they shown that these sequences have the same or related functions. Therefore, the sequences together do not make a proper Markush group because the polypeptides are not related in structure or in function.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1 (a-d), 2-5, 8(a-f), 9-14, 18(a-d), 19-22, 25, and 26 (a-d) have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 1(e, f), 6, 7, 8(g-l), 15-17, 18(e, f), 23, 24, and 26 (e, f) are currently under examination.

Priority is set to the filing date of SN 08/766,528, December 13, 1996. The instant SEQ ID NO: 3 is not found in SN 08/572,645 filed December 14, 1995. Rather, '645 teaches instant SEQ ID NO: 1 encoding Tsukuba-1.

The disclosure is objected to because of the following informalities: The priority information must be updated to include patent numbers on page 1 of the specification.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1(e, f), 6, 7, 8(g-l), 15-17, 18(e, f), 23, 24, and 26 (e, f) are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed polypeptides have not been isolated or purified and therefore read on the polypeptide in nature.

Claims 1(e ,f), 6, 7, 8(g-l), 15-17, 18(e, f), 23, 24, and 26 (e, f) are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The polypeptide encoded by a nucleic acid comprising the nucleotide sequence SEQ ID NO: 3 lacks a specific utility. First, SEQ ID NO: 3 encodes at least 3 different proteins, gag, pol, and env. Review articles in the retroviral art teach that gag is further cleaved into at least matrix (MA), Capsid (CA), and nucleocapsid (NC) (Freed, 2002; J. Virol. 76 (10): 4679-4687; see Fig. 1 for "Generic Gag"). Pol is cleaved into enzymes, and Env cleaved into glycoproteins. In the genome, Gag is further cleaved into p1, p2, and p6. The pol is cleaved into enzymes HIV-1 protease (PR), reverse transcriptase (RT), and integrase (IN), while the env is cleaved into vpu, surface (SU), and transmembrane (TM) envelope proteins (Freed, 1998; Virol. 251:1-15, see Fig. 1A). Besides gag, pol, and env, the HIV-1 genome encodes additional proteins, such as vif, vpr, and nef (Freed, 1998). As in HIV-1, Freed (2002) teaches that gag encodes proteins other than MA, CA, and NC. In mouse leukemia virus (MLV), gag additionally comprises p12; in Rouse sarcoma virus, p2a, p2b, and p10; in Mason-Pfizer monkey virus (M-PMV), p4, p12, and pp24/16; and in equine infectious anemia virus (EIAV), p9. The instant specification is silent as to the function and proteolytic breakdown of polypeptides encoded by SEQ ID NO: 3, having at least 85% identity to SEQ ID NO: 3, or having at least 15 or 20 nucleotides from SEQ ID NO: 3. Indeed, no polypeptides or polypeptides sequences are taught in the specification.

Additionally, human immunodeficiency virus (HIV-1) proteins result in reduced immune system function, the mouse leukemia virus (MLV) proteins result in leukemia, the Rouse sarcoma virus proteins result in cancer, and the equine infectious anemia virus (EIAV) proteins result in anemia, for example. The instant specification is silent regarding the function of proteins encoded by SEQ ID NO: 3, having at least 85% identity to SEQ ID NO: 3, or having at least 15 or 20 nucleotides from SEQ ID NO: 3. Aliyoshi et al. (with inventor Jay Fishman); 1998; J. Virol. 72(5): 4503-4507) teach a retrovirus having 99.9 % identity to SEQ ID NO: 3 (5 mismatches), and encoding the env protein (Fig. 1). Other encoded proteins are not disclosed therein. At page 4503, left col., para. 2, Akiyoshi et al. teach that Type C retroviruses from swine cell lines are known but no disease following infection has been identified.

Therefore, it can be concluded that the polypeptide(s) encoded by SEQ ID NO: 3, having at least 85% identity to SEQ ID NO: 3, or having at least 15 or 20 nucleotides from SEQ ID NO: 3 do not have a specific utility.

The polypeptides have not been taught to have a substantial utility, or real world use. While SEQ ID NO: 3 (having at least 85% identity to SEQ ID NO: 3, or having at least 15 or 20 nucleotides from SEQ ID NO: 3) may be a retrovirus, the specification does not teach the function of the encoded proteins. Thus, one skilled in the art would have to carry out further research to identity the use of these encoded polypeptides.

The specification does not assert any utility for the encoded polypeptides; thus, the polypeptides lack credible utility because no utility is offered.

Claims 1f, 7, 18 (e, f), 23, 24, and 26f are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. These claims are drawn to polypeptides encoded by complementary sequence to SEQ ID NO: 3, having at least 85% identity to SEQ ID NO: 3, or having at least 15 or 20 nucleotides from SEQ ID NO: 3.

DNA is comprised of a sense and antisense strand, also known as a coding and non-coding strand of DNA, with the antisense and non-coding strand art-recognized as the complementary strand. The complementary strand, then, does not encode any polypeptide. Thus, the complementary strand is inoperable in encoding a polypeptide.

Additionally, specific to Claims 18, 23, and 24, base pairs do not encode polypeptides. A base pair refers to a DNA comprising the coding and non-coding strands, annealed or matched A->T and C->G. Thus, the coding strand is not available for transcription when it exists as a base pair with the non-coding strand, and is therefore inoperable.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1(e, f), 6, 7, 8(g-l), 15-17, 18(e, f), 23, 24, and 26 (e, f) are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, credible, or operable, asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1(e, f), 6, 7, 8(g-l), 15-17, 18(e, f), 23, 24, and 26 (e, f) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification and claims do not set forth any structure of or function for the claimed polypeptide encoded by SEQ ID NO: 3, having at least 85% identity to SEQ ID NO: 3, or having at least 15 or 20 nucleotides from SEQ ID NO: 3. Also, this polypeptide is not in hand. Therefore, the specification lacks written description for the claimed polypeptide(s).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1(e, f), 6, 7, 8(g-l), 15-17, 18(e, f), 23, 24, and 26 (e, f) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims refer to "A polypeptide..." As noted above in the rejection under 35 USC 101, retroviruses encode many polypeptides; therefore, it is not clear which polyeptide is being claimed.

Claim 1 refers to "85% identical". The term "identical" is an absolute term, meaning that one thing is identical to another or it is not. Thus, one skilled in the art cannot know what a fraction of identical means.

Claim 18 f refers to "70% homology". The term "homology" is a qualitative term and not a quantitative term. Thus, one skilled in the art cannot know what 70% homology means. Additionally, it is not clear what a corresponding human, , mouse, or primate retrovirus sequence is, or the last five 3' bases may be.

Claims 1f, 7, 18 (e, f), 23, 24, and 26f are drawn to polypeptides encoded by complementary sequence to SEQ ID NO: 3, having at least 85% identity to SEQ ID NO: 3, or having at least 15 or 20 nucleotides from SEQ ID NO: 3. DNA is comprised of a sense and antisense strand, also known as a coding and non-coding strand of DNA, with the

antisense and non-coding strand art-recognized as the complementary strand. The complementary strand, then, does not encode any polypeptide. Thus, one skilled in the art cannot know what polypeptide is encoded in these claims.

Claims 18, 23, and 24 refer to base pairs which do not encode polypeptides. A base pair refers to a DNA comprising the coding and non-coding strands, annealed or matched A->T and C->G. Thus, the coding strand is not available for transcription when it exists as a base pair with the non-coding strand. Thus, one skilled in the art cannot know what polypeptide is encoded in these claims.

In Claim 26, the stringency conditions are not set forth, and the specification does not define the term "stringent conditions". Thus, the claim is indefinite regarding the conditions for hybridization.

Additionally, the claims continue to comprise inventions drawn to non-elected subject matter. Therefore, the Claims are indefinite because they do not particularly point out and distinctly claim the subject matter which the applicant regards as his elected invention

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18(e), 23, and 26(e) are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al. 1992. J. Immunol. 149:1223-1229.

Hayashi et al. teach AKV murine leukemia virus comprising Gly-Phe-Tyr-Val-Cys-Pro-Gly-Pro (amino acids 148-155 in Fig. 5), for example, encoded by nucleotides 325-348 of SEQ ID NO: 3.

Therefore, Hayashi et al. teach a polypeptide encoded by at least 15 bases of SEQ ID NO: 3 (Claim 18(e), 23) and at least 20 bases bases that hybridize to SEQ ID NO: 3 (Claim 26(e)).

No Claims are allowed.

Art of Record:

Banerjee et al. (USP 6,261,806 having priority to August 18, 1998) teach polypeptides encoded by 5620-7533 of SEQ ID NO: 3 except for Asn275Ser – see Banerjee SEQ ID NO: 6.

Galbraith et al. (USP 6,756,227 having priority to Feb. 8, 1999) teach SEQ ID NO: 5 having 17 mismatched amino acids encoded by nucleotides 2307-5741 of instant SEQ ID NO: 3. Galbraith et al. SEQ ID NO : 4 has 13 mismatched amino acids encoded by nucleotides 585-2156 of instant SEQ ID NO: 3. Galbraith et al. SEQ ID NO: 3 shares 77% identity with instant SEQ ID NO: 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER